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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	14

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,171	PATI ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P ri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) 5 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-12* is/are rejected.

7)☒ Claim(s) *10 and 12* is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' election of Specie A (a genomic product which is in a nucleic acid clone) in Paper No. 10, filed 12/26/02, is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 5 is withdrawn from consideration as being drawn to a non-elected specie.

Corrected drawings, filed 4/11/03, have been accepted by the draftsperson.

Claims herein under examination are 1-4 and 6-12.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 6, line 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: On page 4, line 19, "phenotyp" is misspelled. On page 5, line 30, "agains" is misspelled and a comma is missing after the word "gene". Correction of these and any other spelling or grammatical mistakes is requested.

Claim Objections

Claims 10 and 12 are objected to because of the following minor informalities:

In claim 10, line 5, the phrase "to for" does not make grammatical sense.

In claim 12, line 3, the phrase "in as" does not make grammatical sense.

Appropriate correction is requested.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4 and 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

For claims 1, 3, 9, 10 and 11, these claims are rejected due to the inconsistency of exactly what the requests comprise. Due to the comma in claim 1 (line 3) and claim 11 (line 5), the request in these claims appears to comprise of a nucleic acid sequence with the order being separate from the request. In claim 3, due to the semicolon (line 2) and comma (line 3), the request appears to comprise an order with the nucleic acid sequence being separate from the request. Due to the absence of a comma after sequence (claim 9, lines 3 and 5) and (claim 10, line 3), the request in these claims appear to comprise either a sequence alone or both a sequence and an order. While it is understood that these are first and second requests, clarification of whether Applicants intend these two types of requests to contain a sequence and/or an order via careful usage of semicolons and commas is requested. Claims 2, 4, 6-8, and 12 are also rejected due to their direct or indirect dependency from claims 1 and 11.

Claim 4 which depends from claims 1, 2, or 3, recites the phrase "said at least one genomic product" which has antecedent basis in claim 3 (line 3), but lacks antecedent basis in

claims 1 and 2 which both contain "at least *two* genomics products". Appropriate correction is requested to remove this lack of antecedent discrepancy.

Claim 8, line 4, recites the phrase "substantially complementary" which is vague and indefinite. It is unclear what criteria and to what degree this criteria must be met to be considered "substantially complementary." The claim does not adequately define the phrase which could mean the complementarity is 100% similar and of the same length of the sequence, or 90% similar and only a fragment of the sequence, or any other scenario. Clarification of the metes and bound of this phrase via clearer claim wording is requested by providing an appropriate definition of the degree of sequence complementarity.

Claim 8, line 6, recites the phrase "or a homologue thereof" which is vague and indefinite. The claim does not adequately define the phrase which could have any degree of homology to a sequence, including homology resulting from single nucleotide similarity. Clarification of the metes and bound of this phrase via clearer claim wording is requested by providing an appropriate definition of the degree of homology that is intended to be used.

Claim 12 is vague and indefinite, because it does not end in a period.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (P/N 5,841,975) in view of Seilhamer et al. (WO 96/23078).

Layne et al. describe a method and apparatus for sharing integrated services with remote clients involving biological material (abstract, item 200 in Figure 7, and col. 11, lines 55-57). Layne et al. describe a customer generating commands (request) via a computer communication program link and sending specimens to an automated lab (abstract; Figure 4; col. 8, lines 30-35; and col. 15, lines 22-25). Layne et al. describe the customer is enabled to define the processes to be performed by entering information into the program via control tools (col. 8, lines 30-32). Layne et al. describe obtaining and transmitting results, which is reasonably interpreted as more than one product or service, to the remote client (abstract). Layne et al. also describe creating and entering output and analyses for the results (report) into a database as seen in Figure 4. Layne et al. depict this process as circular and continuous (Figure 4) which suggests that multiple, including second requests (note the claims do not require the first and second nucleic acid sequences to necessarily be different), can be made by the customer as stated in claim 3.

Layne et al. describe how the remote customer can have the data stored into a database and request analyses to be performed on data generated by their and other users' data on the database (col. 8, lines 45-51 and col. 11, lines 5-9). Layne et al. do not describe the nucleic acid clone product ordered from the customer which is the noted specie election in the instant application.

Seilhamer et al. describe obtaining cDNA from a customer as well as storing relevant supplier information in a table which is stored in a database (page 9, lines 25-30). Seilhamer et al. describe performing a cloning process on the cDNA (Figure 2 and page 9, lines 31-32). As the claims do not mention that the "at least two genomics products" must be different from each other, Seilhamer et al. describes multiple clones which may or may not be different (page 15, lines 6-10). In Figure 2, Seilhamer et al. depict the cloning process followed by sequencing which is stored in a database (page 14, third paragraph) and sequence comparison (page 15, first paragraph) which is reasonably interpreted to mean that searchable genomic data was created as stated in claim 2. Seilhamer et al. describe the sequences may be compared to known sequences in genetic databases (page 15, first paragraph to page 17, first paragraph). Seilhamer et al. describe during the sequence comparison process, the multiple clones may contain all or parts of the same gene/allele (page 15, first paragraph) which is reasonably interpreted as checking for wholly or partially redundant information within the databases as stated in claim 12. This also suggests the clones may represent a subset of a gene family as stated in claim 6. Seihamer et al. describe that information associated with the steps in Figure 2 (including sequence comparison) is stored in a database (page 6, lines 6-9) which is reasonably interpreted to include the updating step in claim 12.

Layne et al. state their apparatus and method satisfies a need to provide a wide variety of adaptable services to globally-distributed remote clients (col. 15, line 66 to col. 16, line 10). Layne et al. state there is a need to integrate capabilities of available automated equipment to permit processes to be performed instead of solely relying on special-purposes devices (col. 16, lines 1-4). Seilhamer et al. state that most analysis on genetic information was performed using chemical methods in a laboratory (page 1, lines 27-28). Seilhamer et al. state computerized research tools at the time only performed limited comparisons to sequence information and state a need to store and manipulate diverse information involving cDNA sequences and the cells from which they were derived in order for scientists to analyze data efficiently in diagnostic and drug development research (page 1, line 33 to page 2, line 5). A person of ordinary skill in the art would have been motivated to enhance the integrated services stated by Layne et al. by including additional features in the method to further increase the efficiency and availability of research materials, as stated by Seilhamer et al., to globally-distributed remote clients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the nucleic acid clone supplies and associated sequence comparison information (as stated by Seilhamer et al.) in a manner to be available to remote clients (as stated by Layne et al.) as this would provide a more efficient and global use of tools for diagnostic and drug development research as stated by Seilhamer et al. and Layne et al.

Thus, Layne et al., in view of Seilhamer et al., motivate claims 1-4, 6, 9, 11, and 12.

Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (P/N 5,841,975) in view of Seilhamer et al. (WO 96/23078) and Pati et al. (WO 99/37755).

Layne et al. describe a method and apparatus for sharing integrated services with remote clients involving biological material (abstract, item 200 in Figure 7, and col. 11, lines 55-57). Layne et al. describe a customer generating commands (request) via a computer communication program link and sending specimens to an automated lab (abstract; Figure 4; col. 8, lines 30-35; and col. 15, lines 22-25). Layne et al. describe the customer is enabled to define the processes to be performed by entering information into the program via control tools (col. 8, lines 30-32). Layne et al. describe obtaining and transmitting results, which is reasonably interpreted as more than one product or service, to the remote client (abstract). Layne et al. also describe creating and entering output and analyses for the results (report) into a database in Figure 4. Layne et al. depict this process as circular and continuous (Figure 4) which suggests that multiple, including second requests (note the claims do not require the first and second nucleic acid sequences to necessarily be different), can be made by the customer as stated in claim 3. Layne et al. describe how the remote customer can have the data stored into a database and request analyses to be performed on data generated by their and other users' data on the database (col. 8, lines 45-51 and col. 11, lines 5-9). Layne et al. do not describe the order from the customer which is a nucleic acid clone (the noted specie election in this application) or the use of a recombinase mediated process.

Seilhamer et al. describe obtaining cDNA from a customer as well as storing relevant supplier information in a table which is stored in a database (page 9, lines 25-30). Seilhamer et

al. describe a cloning process is performed on the cDNA (Figure 2 and page 9, lines 31-32). As the claims do not mention that the "at least two genomics products" must be different from each other, Seilhamer et al. describes multiple clones which may or may not be different (page 15, lines 6-10). In Figure 2, Seilhamer et al. depict the cloning process followed by sequencing which is stored in a database (page 14, third paragraph) and sequence comparison (page 15, first paragraph) which is reasonably interpreted to mean that searchable genomic data was created as stated in claim 2. Seilhamer et al. describe the sequences may be compared to known sequences in genetic databases (page 15, first paragraph to page 17, first paragraph). Seilhamer et al. describe the multiple clones may contain all or parts of the same gene/allele (page 15, first paragraph) which is reasonably interpreted as checking for wholly or partially redundant information within the databases as stated in claim 12. This also suggests the clones may represent a subset of a gene family as stated in claim 6. Seihamer et al. describe that information associated with the steps in Figure 2 (including sequence comparison) is stored in a database (page 6, lines 6-9) which is reasonably interpreted to include the updating step in claim 12.

Pati et al. describe a method for targeting sequence modifications in one or more genes of a related family of genes using enhanced homologous recombination techniques (page 1, lines 6-7). Pati et al. describe a method of isolating and identifying members of homologous sequence families (page 1, lines 7-9). Pati et al. describe the provision of a composition comprising a recombinase and a plurality of pairs of substantially complementary single-stranded targeting polynucleotides and isolating the nucleic acid (page 4, fourth paragraph to page 5, third paragraph).

Layne et al. state their apparatus and method satisfies a need to provide a wide variety of adaptable services to globally-distributed remote clients (col. 15, line 66 to col. 16, line 10). Layne et al. state there is a need to integrate capabilities of available automated equipment to permit processes to be performed instead of relying solely on special-purposes devices (col. 16, lines 1-4). Seilhamer et al. state that most analysis on genetic information was performed using chemical methods in a laboratory (page 1, lines 27-28). Seilhamer et al. state computerized research tools at the time only performed limited comparisons to sequence information and there was a need to store and manipulate diverse information involving cDNA sequences and the cells from which they were derived in order for scientists to analyze data efficiently in diagnostic and drug development research (page 1, line 33 to page 2, line 5). Pati et al. state techniques using enhanced homologous recombination were recently discovered which allow sequence modifications to be specifically targeted to virtually any genomic position (page 3, paragraph three). A person of ordinary skill in the art would have been motivated to enhance the integrated services stated by Layne et al. by including additional features in the method to further increase the efficiency and availability of research materials as stated by Seilhamer et al. to globally-distributed remote clients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the nucleic acid clone supplies and associated sequence comparison information (as stated by Seilhamer et al.) using a specific cloning process involving recombinase in order to target specific genes in diseased organisms (as stated by Pati et al., page 6, last paragraph) in a manner that is available to remote clients (as stated by Layne et al.) as this would provide a more efficient and global use of tools for diagnostic and drug development research as stated by Seilhamer et al. and Layne et al.

Thus, Layne et al., in view of Seilhamer et al. and Pati et al., motivate claims 1-4 and 6-12.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 24, 2003

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER